Review of Draft Report of ECOFRAM

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My comments are directed to the Aquatic aspects of the ECOFRAM report.

General

The EPA OPP is to be congratulated for undertaking a program to revise the methods for conducting ecological risk assessments for pesticides. The initiative to revise the ecological assessment process for pesticides was much needed, in light of the advances in the state of the sciences relating to understanding the fates of compounds in the environment and the toxic effects of pesticides, as well as the advances in models of these processes. The ECOFRAM committee has produced a comprehensive report that outlines a sound tiered approach for conducting risk assessments for pesticides. The proposed framework includes the most current understanding of fates and effects processes and applies the most advanced procedures for the analysis. It is likely that the process will need to be revised again in the future, as more information on and understanding of fates and effects processes become available. The advances in computing capabilities and modeling algorithms have allowed the proposed structure to be developed. It is expected that advances in these areas will continue and that OPP should be prepared to assess and adopt as appropriate future advances.

There are a number of missing sections in the report. I reviewed the content as well as possible, considering a number of sections were yet to be incorporated.

There are a number of typos in the text. I have edited the text and marked these on the hard copy.

The graphics were not very readable in the hard copy or the electronic version of the report. If I could not read them others will probably have similar difficulties.

There is no such word as “percentile”. This term should be replaced with either “percentage” or “centile”, as appropriate in the text.

Avoid starting sentences, especially topic sentences with a citation to literature or a table or figure. Use subject–verb format.

The first three chapters were well organized and written, but chapter 4 is poorly organized and uneven. The white papers need to be merged somehow into a coherent discussion of the issues.

In the introduction, I would add a section that states that some degree of change from natural conditions is expected in the aquatic systems in agricultural areas. Acceptance of these changes is a social decision. The degree of acceptable change due to exposure to pesticides needs to be made

in the context of changes in populations and community structure due to physical disturbances, changes in nutrient and temperature regimes.

Currently, the two main sections of the report, exposure and effects are not well integrated together, relative to how the tow processes will be integrated in each tier. This type of integration needs to be superimposed on the current report structure.

Answers to specific questions given in the charge to ECOFRAM workshop panel members.

1. Is the draft report scientifically sound? If not, please explain and provide specific suggestions on how to improve the report and make it scientifically sound.

It is my opinion that the draft report is scientifically sound. Use of the proposed framework will greatly enhance the risk assessment process. The proposed framework will provide more flexibility and realism in the risk assessment process. The tiered approach is rational and allows for a degree of conservatism when information is lacking or uncertain. The process rewards the collection of more detailed information on the fates and effects of pesticides and allows the use of field monitoring data in the risk assessment process. I found no fatal errors in the rationale or approach proposed. I will provide specific comments on the details of the proposed approach in following sections. The greatest limitation of the approach will be the requirement for additional input data, which for relatively new compounds, especially those with novel chemistries may be lacking. In these cases, a default to the more conservative lower tiers is appropriate.

The proposed framework is based on the ARAMDG and EPA Ecological Risk Assessment framework documents, both of which provide appropriate guidance for advancements in the risk assessment of pesticides.

The proposed framework allows for an iterative process of refinements of the assessments and thus regulation and mitigation. This is a very positive attribute.

The tiered approach is scientifically and economically sound.

The “tool box” approach for the third and fourth tiers will give greater flexibility to the assessment process and allow for greater realism an serve as a mechanism to foster communication and dialogue between the risk assessors and risk managers.

The suggested probabilistic approaches, especially for the estimation of environmental concentrations will improve the accuracy of the estimates and provide greater realism to the assessments. This, in turn will reduce uncertainty and increase user confidence in the process.

The risk assessment process will always be uncertain. The inclusion of the use of mesocosms, and field trials as well as monitoring information will reduce the uncertainty that is inherent in the process. The advantages and disadvantages of these approaches is well articulated in the report and will serve as useful guidance for practitioners as they apply these approaches. In addition to these approaches, I would suggest limited biological monitoring to assure that national criteria for the protection of aquatic life is being achieved in agricultural areas where multiple agricultural chemicals are being applied.

The proposed framework will encourage the collection of additional information. I endorse the collection of a minimum data set. This should be done in a manner that is compatible with the data requirements in Europe.

The inclusion of ecological considerations and relevancies is a very positive attribute of the proposed framework. The inclusion of population modeling will take some time to develop so that it can be integrated into the assessment process, but working toward this goal is encouraged. The consideration of concepts such as pulsed exposures and return frequencies in the framework are both deemed to be positive innovations.

The listings and descriptions of the data requirements, utility and limitations of the various models is very comprehensive, well organized and written. This is a very useful portion of the report.

The use of complete concentration-response information in the assessment process is a positive suggestion of the report.

The suggestion to use benchmarking for compounds of similar mechanisms of action is a good one. This approach will allow more detailed information to be collected for some compounds and applied to others in the risk assessment process.

The discussion of current models and proposed models and their advantages and disadvantages and levels of accuracy is excellent.

The section of the exposure chapter on development and use of data bases is excellent and I endorse the continued development of these tools. Standardization of data reporting and making it easily available to risk assessors and modelers would be very useful. Pooling available data, as suggested would be very useful.

The RADAR model seems to be particularly useful and I endorse it continued development.

I endorse the “tool box” approach to the higher order tiers. This will allow the necessary flexibility to develop scenarios and apply appropriate techniques on a chemical and possibly a site-specific basis.

I concur with all of the suggestions to improve the current methodologies and endorse the long-term development that is suggested.

I endorse the development of the GIS data bases for use in risk assessment. This will be the next great advance in the predictive capabilities of risk assessments.

I concur with the use of exposure scenarios to assess the potential of mitigation strategies. However, I also suggest that monitoring be part of the decision strategy.

I concur with the use of mesocosms and field-scale studies to refine model parameters and for use as an efficient multi-species test.

I endorse the use of sensitivity analyses to refine models of exposure.

The PWG land use-land cove classification was an excellent exercise and should serve as a model for future work in the area of GIS.

I endorse the use of time to effects models. However, I would suggest that both duration and intensity of exposure are important and that both types of information should be collected so that toxicity curves can be developed. This information can also be used in reciprocity analyses, which are critical for the development and scaling of appropriate exposure scenarios and monitoring schemes. The use of time to effects information will make it possible to develop population level models and interpret return frequencies for a give population. This the collection of this information will allow more accurate and useful assessments. However, the collection of the additional information will not likely add sufficiently to the body of information soon enough to allow use of these techniques in the near future. Furthermore this information will not be readily useful in the probabilistic estimation of among-species sensitivities. I think that it is more important to obtain more information on additional species than to obtain more information on the time to effects for individual species. While the TTE model is a useful one, it is doubtful if this will reduce uncertainty in ecological risk assessment significantly in the near term. This is especially true for insecticides that are acutely toxic and have small acute to chronic ratios (less than 10).

I endorse the proposal to use joint probability curves, but suggest that these should only be used in conjunction with a return frequency analysis and keystone species assessment.

I endorse the use of the probabilistic approach to estimating species sensitivities, but this approach should not be used as an absolute measure of a protective level, but as a part of a weight of evidence approach. In particular, this approach is most useful in identifying the most sensitive types of species that might be candidates for further analysis relative to their ecosystem function, recovery time or population analyses, or use in monitoring programs.

The discussion of effects of time varying repeated exposures is well done, but needs to be expanded to include a discussion of reciprocity and inter-period return frequencies, in the context of rates of damage and repair as well as pharmaco-kinetic modeling. There are a number of publications that discuss these issues that should be included in the discussion presented.

2. Did the ECOFRAM Workgroup address the "Charge to the Terrestrial and Aquatic Workgroups" identified in the background document "Evaluating Ecological Risk: Developing FIFRA Probabilistic Tools and Processes" (Attachment #3)? If not, please explain why not and provide specific suggestions on how the "Charge" could be addressed.

Yes, the Aquatic Workgroup addressed the charge. I found that the proposed framework is a rational "state of the science" methodology.

The proposals for additional exposure scenarios is endorsed, but these proposed scenarios need to be validated. The conclusions and guidance about the use of exposure models is well stated and accurate and supports the conclusion that additional work on model validation is necessary.

3. What are the limitations for predicting risk using the approach described in the draft

report? Please provide specific suggestions.

3a. All of the recommendations are valid, but it will not be possible to implement some of the suggestions in the near future. In some cases additional algorithms will be necessary and in other cases, a great deal more information will be needed before the proposed framework can be implemented. In yet other cases, the information is available, but has not yet been complied into a format that will be readily useable. For instance, the use of satellite GIS information will provide the necessary information for landscape level assessments, however, much of this information is yet to be complied in a manner so that it will be available for use in the risk assessment process. Implementation of data acquisition programs such as the MERCURY program funded by NASA and being developed by the Environmental Sciences Division of Oak Ridge National Laboratory will greatly facilitate the compilation and acquisition of the necessary information for landscape-level risk assessment. Toward this end, inter-agency cooperation to develop these systems, facilitate access and disseminate the information will be necessary.

3b. I endorse the use of population-level models to bridge the gap between the screening -level assessments that are meant to protect and higher tiers that are meant to actually predict the potential for and magnitude of potential effects. While it is true that the theory and application of these types of models has been greatly improved in recent years, it is unlikely that these types of models will be useful in more than an accessory role in higher tiers as part of a weight of evidence approach to risk assessment. In particular, some guidance needs to be provided as to the types of models that can be used and the parameter ranges that would be acceptable in the models. Otherwise, the range of possible outcomes will be so great as to render such models useless in the risk assessment process. It is my opinion that the current state of such models and the ultimate predictive power of such models is limited and will not be useful in predicting the responses of complex communities, especially in the light of the various compensatory mechanisms that are possible in such systems. Instead, these models will be useful in scaling and interpreting the potential of adverse effects in aquatic systems exposed to pesticides.

4. Taking into account your answers to the three questions above, what areas of the report need to be strengthened? If possible, please provide specific recommendations for how to strengthen the report.

In general, the report is very well conceived, organized and written. It is comprehensive and addresses all of the pertinent issues relative to the current state of the science, risk assessment practices and innovative suggestions to improve the risk assessment procedures for pesticides in aquatic systems. The chapter on exposure assessment is better organized and written than the chapter on effects metrics. Chapter 4 needs to be written in a more integrated manner. Currently the individual white papers, while useful are not well integrated and there is no coupling of the deficiency in current risk assessment methodologies and the proposed improvements, such as there is in the chapter on exposure.

The section on uncertainties presented in chapter 4 is very good, but needs to be integrated into a discussion that presents suggested improvements to the risk assessment process, such as was done in the chapter on exposure estimates. Chapter 4 is unfocused and diffuse and needs to be organized

around themes, instead of presenting stand-alone white papers on different subjects. The chapter on exposure is well conceived, organized and written, chapter 4 should be organized in a similar manner such that it is easy to see the current methodology and the proposed improvements. This should include a discussion of the advantages and disadvantages of the suggested changes.

5. At what point in the risk assessment process is the certainty level high enough to support the consideration of risk mitigation? What is the minimum level of technical information and scientific understanding that is necessary to evaluate whether risk mitigation would be necessary and /or effective?

Risk mitigation should not be considered until at least a tier III risk assessment has been completed. Earlier tiers do not give sufficient resolution or realistic estimates of exposure to determine that risk mitigation is necessary or to evaluate the potential reduction in exposure that a particular mitigation strategy would provide.

It is my opinion that basin-scale models will never be sufficiently accurate to provide a prediction of actual concentrations. Similarly, these models will not, by them selves provide a sufficient level of certainty near the threshold for effects to allow a decision to be made without some level of uncertainty. Only if hazard quotients are less than 0.001 would I be comfortable in determining that no risk is likely. The uncertainty associated with each parameter in the model and the relatively large number of parameters in the most recent exposure models are such that the propagation of errors will make estimates that are more accurate than order of magnitude very unlikely. Therefore, these models will never approach the level of certainty to predict the success of mitigation measures. It is suggested that field-scale monitoring be used to determine the success of mitigation practices on a site-by site basis, or at least on a regional scale.

P 3-25 I agree that screening level models are qualitative and provide information on relative exposures among compounds. This level of assessment is not sufficient for regulatory decisions.

Specific Comments

P 2-10 Why specify the 95th centile. Why not give the entire range of probabilities of observation?

P 2-15 In the table, what is meant by "a single value that is ideally 90% of the expected Tier II results"? How would one know in Tier I what values would be found in Tier II. This does not make any sense to me. If the results of Tier II were know when the Tier I Assessment was conducted, it would obviate the need to conduct the Tier I assessment. This comment is made several times in the report. The meaning of this statement needs to be clarified.

P 2-15 It is not clear why the range of concentrations becomes greater with higher tiers. It seems that this need to be better explained. Specifically, the range of possibilities needs to be separated from the range of uncertainty.

P 2-18 The output from GEENEC does not include 60 days.

P 2-22 On line 22 some additional description is needed. Would these be square-wave function? How these moving averages are derived will have a major impact on the results of the analysis.

P 2-23 If probabilities are calculated for "events" in tier II, they need to be interpreted in the context of return frequencies. One event every 10 years could be sufficient to keep a viable community from developing in some ecosystems. In others, a return frequency of a few days or weeks might not result in long-term effects on populations or the community. This concept is discussed in chapter 4, but it is not fully developed. This is an important concept, that is at the heart of protecting aquatic communities so it needs to be completely developed and presented in the report.

P 3-85 A CD-ROM was mentioned, but I did not have access to this so can not evaluate the data set described.

P 3-86 I concur with the plea for standardization of data bases and making them more widely available through the internet.

P3-109 The document provides an appropriate balance between what is currently available and what would be ideal, which maintains flexibility and encourages further development of assessment tools.

P3-110 Use of GEENEC as proposed for tier I exposure assessments is appropriate.

Suggestions

1. The use of the semi-probabilistic methods of Stephan et al., 1985 as adapted for use in the Great Lakes Water Quality Initiative is suggested to derive estimates for the final acute and final chronic values. This will give probabilistic estimates without the need for hundreds of toxicity tests on different species.

2. Inclusion of additional single-species toxicity tests in tier II would allow refinement of the estimate of the hazard as well as refining the estimate of exposure.

3. Conducting a reciprocity analysis as part of the time to effect models is suggested. This information would not only allow for more flexibility in determining the type of assessment to conduct, it would allow the determination of the most appropriate moving average methods for the exposure assessment.

4. Aquatic organisms are often exposed to multiple toxicants and stressors. This is not addressed in current risk assessment methodologies used by OPP and not specifically addressed in either the section on exposure analysis or effects analyses. This issue needs to be addressed by ECOFRAM. In particular, I suggest that they consider concentration addition methodologies for compounds with similar modes of action and response-addition methodologies when different mechanisms are indicated. The theoretical basis for both of these techniques is well developed and has been tested for some aquatic organisms for

pesticides.